IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Manne Satyanarayana REDDY et al. Examiner: R. L. Anderson

Application No.: 10/629,316 Art Unit: 1626

Filed: July 29, 2003

For: CRYSTALLINE FORM OF LOSARTAN POTASSIUM

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

RESPONSE

In response to the Office Action that was mailed on September 29, 2005 for the subject application, applicants respectfully request reconsideration of the imposed restriction requirement, based on the following discussion.

An election has been required of one of two groups of claims for examination, as follows:

I. Claims 1-30, directed to crystalline Form III of the compound losartan potassium; and

II. Claims 31-60, directed to processes for preparing Form III of the compound losartan potassium.

This restriction requirement was predicated on a perceived distinctness of the product and process claims, apparently including a determination that the claimed process can be used to make different products, such as the Form I of losartan potassium described in U.S. Patent 5,608,075 to Campbell, Jr. et al.

Referring to column 14 of the cited patent, it appears that Form I of the compound was actually prepared in a stability experiment, by equilibrating solid Form II in various liquids overnight. There is no information in Example 10 that would indicate a dissolution and recrystallization of losartan potassium compound in any solvent. In Example 9 of this patent, Form I of the compound was recovered by evaporating a

solvent azeotrope from an aqueous cyclohexane/isopropanol mixture containing losartan potassium; when the water content of the residue became <0.05%, the residue was cooled to generate Form I crystals. An unspecified form of the compound was prepared in Example 4, where a concentrated aqueous solution of losartan potassium was diluted with isopropanol to cause product crystallization.

Those skilled in the relevant art are aware that different polymorphic forms of a compound are formed under different conditions. Solvents that are useful for crystallizing a form generally will not readily produce another form. The difficulty encountered in predicting whether an additional form is possible for any compound, and predicting a suitable process that could generate a new form, is discussed in a number of recent publications, including the article by A. Goho, "Tricky Business," *Science News*, Vol. 166, No. 8, pages 122-3, August 21, 2004. An eight-page website reprint of this article is attached. It is quite unlikely that the same process could ever produce both of Form I and Form III of losartan potassium, and applicants respectfully request that some evidence be provided to justify the determination, if this requirement is maintained.

Policy for imposing restriction requirements has been established by M.P.E.P. § 803, as follows:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)).
>
> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

In a subsequent paragraph of the same section, it is stated:

> For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.

For this restriction requirement, no determination has been made that the two groups of claims are able to support separate patents, and the classification for the two

"inventions' was described as "class 548, subclass 252." Since the polymorphic forms are of a single chemical compound, both of the claimed "inventions" apparently will require the exact same search, before substantive examination. There is no possibility that an undue burden will be encountered in examining all of the claims together, and the requirement therefore does not comply with guidelines established by the Office.

As no proper basis for the restriction requirement is apparent, and the Office guidelines for requiring restriction have not been observed, applicants submit that the requirement is entirely improper and should not be maintained. However, if the requirement is maintained, applicants hereby provisionally elect to proceed with examination of the claims of Group I (claims 1-30).

To complete the claim for priority under 35 U.S.C. § 119, applicants are submitting herewith a certified copy of India Patent Application 568/MAS/2002 that was filed on July 29, 2002.

If a telephonic or personal interview with the undersigned attorney will assist with resolution of issues regarding this application, please use the contact information below to arrange for an interview.

Respectfully submitted,

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